

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

PCT

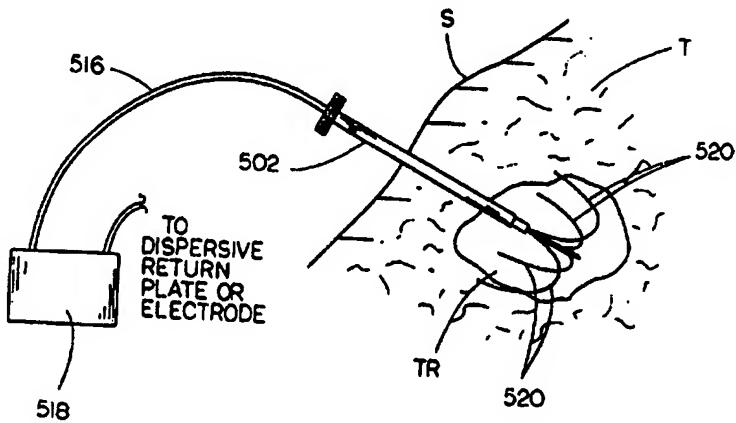
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/39		A1	(11) International Publication Number: WO 96/29946 (43) International Publication Date: 3 October 1996 (03.10.96)
(21) International Application Number: PCT/US96/03817		(81) Designated States: AL, AM, AT, AU, AZ, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, IS, JP, KE, KG, KP, KR, KZ, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, UZ, VN, ARIPO patent (KE, LS, MW, SD, SZ, UG), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).	
(22) International Filing Date: 20 March 1996 (20.03.96)		Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>	
(30) Priority Data: 08/410,344 24 March 1995 (24.03.95) US			
(71) Applicant: BOARD OF REGENTS OF THE UNIVERSITY OF NEBRASKA [US/US]; 3835 Holdrege Street, Lincoln, NE 68503 (US).			
(72) Inventors: LeVEEN, Robert, F.; 600 SO. 42nd Street, Omaha, NE 68198-1045 (US). FOX, Randy; 600 SO. 42nd Street, Omaha, NE 68198-1045 (US).			
(74) Agent: FREDERIKSEN, Mark, D.; Zarley, McKee, Thomte, Voorhees & Sease, Suite 3200, 801 Grand Avenue, Des Moines, IA 50309-2721 (US).			

(54) Title: APPARATUS FOR ABLATION OF TISSUE MASSES



(57) Abstract

A volumetric tissue ablation apparatus (10) includes a probe (12) having a plurality of wires (24) journalized through a catheter (26) with a proximal end connected to the active terminal (16) of a generator (14) and a distal end projecting from a distal end of the catheter (26). The probe wire distal ends (24a) are arranged in an array with the distal ends (24a) located generally radially and uniformly spaced apart from the catheter distal end (26a). A conductor (22) connected to the return terminal (18) of the generator is located relative to the probe wire array (28) to form a closed electrical circuit through tissue to be ablated. Preferably, the probe wire array (28) includes ten wires, each formed in an arch from the catheter distal end (26a). The conductor (22) can be either a conventional ground plate (20) upon which the tissue is supported, or a conductor wire extending through the probe (12) and electrically insulated from the probe wires (24).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AM	Armenia	GB	United Kingdom	MW	Malawi
AT	Austria	GE	Georgia	MX	Mexico
AU	Australia	GN	Guinea	NE	Niger
BB	Barbados	GR	Greece	NL	Netherlands
BE	Belgium	HU	Hungary	NO	Norway
BF	Burkina Faso	IE	Ireland	NZ	New Zealand
BG	Bulgaria	IT	Italy	PL	Poland
BJ	Benin	JP	Japan	PT	Portugal
BR	Brazil	KE	Kenya	RO	Romania
BY	Belarus	KG	Kyrgyzstan	RU	Russian Federation
CA	Canada	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	KZ	Kazakhstan	SG	Singapore
CH	Switzerland	LI	Liechtenstein	SI	Slovenia
CI	Côte d'Ivoire	LK	Sri Lanka	SK	Slovakia
CM	Cameroon	LR	Liberia	SN	Senegal
CN	China	LT	Lithuania	SZ	Swaziland
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	LV	Latvia	TG	Togo
DE	Germany	MC	Monaco	TJ	Tajikistan
DK	Denmark	MD	Republic of Moldova	TT	Trinidad and Tobago
EE	Estonia	MG	Madagascar	UA	Ukraine
ES	Spain	ML	Mali	UG	Uganda
FI	Finland	MN	Mongolia	US	United States of America
FR	France	MR	Mauritania	UZ	Uzbekistan
GA	Gabon			VN	Viet Nam

APPARATUS FOR ABLATION OF TISSUE MASSES

Technical Field

The present invention relates generally to radio frequency electrodes for tissue ablation, and more particularly to an improved RF electrode having a spreading array of wires to ablate large volumes of tissue.

Background of the Invention

The liver is a common repository for metastasis from many cancers, including those of the stomach, bowel, pancreas, kidney, and lung. In colorectal cancer the liver is the initial site of spread in more than one-third of patients, and is involved in more than two-thirds at the time of death. While patients with untreated colorectal metastasis to the liver have no five year survival, patients undergoing surgical resection have approximately a 25-30% five year survival. Unfortunately, only a limited number of patients are candidates for surgical resection.

Cryosurgery is also used for the treatment of hepatic metastasis. Cryosurgery, which relies on a freeze-thaw process to nonselectively kill cells, has been found equally effective as surgical resection but is more tissue sparing. While an improvement over open surgical tissue resection, cryosurgery still suffers from disadvantages. It is an open surgical procedure, requires placement of up to five relatively large probes, and can only be applied to a limited number of lesions. While percutaneous probes are being developed, they are currently capable only of treatment of smaller lesions. Typical lesions common to colorectal metastasis, however, are relatively large. Therefore, the outlook for percutaneous cryotherapy is guarded.

A number of investigators have used radio frequency hyperthermia with placement of external electrodes, for the treatment of liver cancers. Tumor cells are known to be more sensitive to heat than normal cells, and externally applied regional hyperthermia delivered with radio frequency tends to

ablate the tumor while sparing the normal tissue of significant damage. While this therapy improves the response to systemic chemotherapy, it has uncertain benefit for long-term survival. One limitation of hyperthermia is that it is difficult to heat the tumors to a lethally high temperature. Moreover, tumor cells tend to become thermoresistant if they survive early treatments.

Percutaneous laser hyperthermia has also been used for primary and metastatic liver cancer. Laser fibers are introduced through needles, under ultrasound guidance. The lesions generated by laser are represented by hyperechoic foci on the real time ultrasound images, which can be used to monitor the size of the lesion. Low energy single fiber systems, which do not require a cooling system along the fiber, can generate areas of necrosis limited to approximately 15 mm diameter. Such small diameters are insufficient for the vast majority of lesions encountered clinically thus requiring multiple fiber placement and prolonged procedure times.

Radio frequency (RF) hyperthermia, using a standard electrosurgical generator and a fine needle partially sheathed in plastic, has also been proposed for the treatment of liver and other solid tumors. In one system, the apparatus was capable of generating lesions of approximately 1x2 cm in a pig liver. In order to produce larger treatment volumes with a single needle, high currents and temperatures have been employed, but produce charred and carbonized tissue, without enlarging the tissue volume being treated. To treat a larger lesion, multiple needle passes in different locations would be needed. In preliminary testing, this system established a 75% survival at 40 months.

It can therefore be seen that the treatment of primary and metastatic liver tumors and other solid tumors elsewhere in the body, remains problematic. Surgery is effective, but only a small percentage of affected patients are candidates. Cryotherapy has had improved results, but its applicable patient population is essentially the same as that for

surgery. The percutaneous methods have the virtue of being less invasive, so they can be appropriately used for a larger spectrum of patients, but current percutaneous methods all suffer from a limited ability to ablate a large volume of tissue in a single procedure with a single probe passage.

Summary of the Invention

It is therefore a general object of the present invention to provide an improved electrosurgical method and probe deployable in a percutaneous procedure that will produce a large volume of thermally ablated tissue with a single deployment.

It is a further object that such methods and probes should be useful in open surgical as well as percutaneous procedures.

Another object is to provide an electrosurgical probe which will provide uniformly treated tissue within a large volumetric lesion.

Still another object of the present invention is to provide a percutaneous electrosurgical probe which requires only a small access hole but provides for large volumetric tissue ablation.

Still another object is to provide an electrosurgical probe which avoids the problems of charring and carbonization common with single needle probes.

These and other objects will be apparent to those skilled in the art.

The present invention provides both methods and apparatus for the radio frequency (RF) treatment of a specific region within solid tissue, referred to hereinafter as a "treatment region". The methods and apparatus rely on introducing at least two electrodes, and usually at least three electrodes to a target site within the treatment region. After reaching the target site, the plurality of electrodes are deployed within the solid tissue, usually in a three-dimensional array and preferably in a configuration which conforms to or encompasses the entire volume of the

treatment region, or as large a portion of the volume of the treatment region as possible. More preferably, the adjacent electrodes are evenly spaced-apart from each other (i.e., pairs of adjacent electrodes will be spaced-apart in repeating pattern) so that application of RF current through the electrodes will result in generally uniform heating and necrosis of the entire tissue volume being treated. Advantageously, the use of multiple electrodes to treat a relatively large tissue volume allows the RF energy to be applied with a lower current density (i.e., from a larger total electrode area) and therefore at a lower temperature in the tissue immediately surrounding the electrode. Thus, charring and carbonization of tissue (which has heretofore been associated with the use of single electrode systems) is reduced. The uniform treatment of a large volume of tissue reduces the number of electrode deployments which are necessary for treating a tissue region of any given size.

In a first particular aspect, the method of the present invention comprises introducing at least two electrodes through solid tissue to a target site within a treatment region. The at least two electrodes are maintained in a radially constrained or collapsed configuration as they are advanced through the tissue to the target site and are then deployed from the target site further into the treatment region in a desired divergent pattern. RF current flow is then established between the at least two electrodes (i.e., bipolar) or among at least the two electrodes and a separate return electrode (i.e. monopolar). The monopolar return electrode will have a surface area which is sufficiently large to dissipate any electrosurgical effect. The at least two electrodes may be deployed by a variety of specific techniques. For example, a sheath may be initially placed using an obturator or stylet to the target site in a conventional manner. After removing the obturator or stylet, the electrodes can be introduced through the sheath and advanced from the distal end of the sheath into the solid tissue. Optionally, the electrodes may be disposed in or on

an elongate member, such as a tube which reciprocatably receives the electrodes. The electrodes may then be advanced from the tube, or alternatively the tube may be withdrawn proximally from over the electrodes prior to advancement of the electrodes from the sheath into the tissue.

In a second specific aspect, the method of the present invention comprises advancing at least three electrodes from a target site within the treatment region. The electrodes diverge in a three-dimensional pattern, preferably with individual electrodes being evenly spaced-apart to provide for uniform volumetric treatment, as discussed above. Treatment is then performed by passing RF current among the at least three electrodes or between said three electrodes and a return electrode. Preferably, the method will employ more than three electrodes, often deploying at least five electrodes, preferably employing at least six electrodes, frequently employing at least eight electrodes, and often employing at least ten electrodes or more. It will be appreciated that a larger number of individual electrodes can enhance the uniformity of treatment while limiting the amount of power (current density) emitted from any single electrode, thus reducing the temperature in the immediate region of the electrode(s). Optionally, the at least three electrodes may be everted, i.e. turned first in a radially outward direction and then in a generally proximal direction, as they are advanced from the target site. The use of such multiple, everted electrodes provides a preferred array for treating relatively large tissue volumes. In particular, arrays of everted electrodes will provide current and heating in generally spherical volumes which will more closely match the spherical or ellipsoidal geometries of the typical tumor or other lesion to be treated. In contrast non-everted electrode arrays will often effect a conical or irregular treatment volume which may have less widespread applicability.

In a first aspect of the apparatus of the present invention, a probe system comprises an elongate member having

a proximal end and a distal end. At least two solid-tissue-penetrating electrode elements are reciprocatably disposed on or in the elongate member so that they may be advanced into tissue after the elongate member has been introduced through solid tissue to a target site in or near the treatment region. A means for introducing the elongate member through tissue to the target site is also provided. The means may take a variety of forms, including a sheath and obturator (stylet) assembly which may be used to provide the initial penetration. Alternatively, a self-penetrating element may be provided directly on the elongate member. Other conventional devices and techniques of the type used for introducing shafts and other elongate members to solid tissue may also be employed.

The tissue-penetrating electrode elements may comprise wires which are received within an axial lumen of the elongate member. For example, the wires may be bundled together over a proximal portion thereof, but remain separate and shaped over their distal portion so that they diverge in a selected pattern when advanced into tissue. Usually, the wires will be advanced directly from the elongate member (when the elongate member is left inside the sheath or the sheath is withdrawn), but could alternatively be advanced from the sheath when the elongate member is withdrawn proximally from over the electrodes prior to penetration of the electrodes into the tissue.

In a second aspect of the apparatus of the present invention, a probe system comprises an elongate member having a proximal end and a distal end, and at least three solid-tissue penetrating electrode elements reciprocatably attached to the elongate member. The at least three electrodes are configured to diverge in a three-dimensional pattern as they are advanced in a distal direction from the elongate member. Usually, the elongate member is a tube having an axial lumen which reciprocatably receives the tissue-penetrating electrode element, and the electrode elements comprise individual wires which may be bundled as described above.

The distal ends of the wires or other electrode elements are preferably shaped so that they will assume a radially constrained configuration while present in the axial lumen of the tube and will assume a radially divergent configuration when axially extended from the tube. In a preferred configuration, the distal ends of at least some of the wires are shaped so that they assume outwardly everted configuration as they are axially extended from the tube or other elongate member. The probe system may include one, two, or more groups of at least three electrodes which are axially spaced-apart from each other. In particular, such axially spaced-apart groups of electrodes may extend from the distal end of the elongate member or may be distributed along the elongate member and individually extendable to assume the desired three-dimensional configuration. Preferably, each group of tissue-penetrating wires or other electrode elements will include more than three electrodes, as described generally above.

Brief Description of the Drawings

Figure 1 is a side elevational view of the tissue ablation apparatus of the present invention;

Figure 2 is an end view of the apparatus of Figure 1;

Figure 3 is a sectional view through tissue, showing the prior art affects of a single needle probe;

Figure 4 is a sectional view through tissue showing the results of the probe of the present invention;

Figure 5 is a side perspective view of a second embodiment of the probe of the present invention;

Figure 6 is a side perspective view of a bipolar embodiment of the invention;

Figure 7 is a side perspective view of a second bipolar probe; and

Figure 8 is a side perspective view of a third bipolar probe.

Figure 9-14 illustrate use of an exemplary probe system according to the present invention in RF treatment of a target region of solid tissue.

General Description of the System of the Present Invention

Systems according to the present invention will be designed to introduce a plurality of electrode elements to a treatment region within patient solid tissue. The treatment region may be located anywhere in the body where hypothermic exposure may be beneficial. Most commonly, the treatment region will comprise a solid tumor within an organ of the body, such as the liver, kidney, pancreas, breast, prostate (not accessed via the urethra), and the like. The volume to be treated will depend on the size of the tumor or other lesion, typically having a total volume from 1 cm^3 to 150 cm^3 , usually from 1 cm^3 to 50 cm^3 , and often from 2 cm^2 to 35 cm^2 . The peripheral dimensions of the treatment region may be regular, e.g. spherical or ellipsoidal, but will more usually be irregular. The treatment region may be identified using conventional imaging techniques capable of elucidating a target tissue, e.g. tumor tissue, such as ultrasonic scanning, magnetic resonance imaging (MRI), computer-assisted tomography (CAT), fluoroscopy, nuclear scanning (using radiolabeled tumor-specific probes), and the like. Preferred is the use of high resolution ultrasound which can be employed to monitor the size and location of the tumor or other lesion being treated, either intraoperatively or externally.

Systems according to the present invention will employ a plurality of tissue-penetrating electrodes, typically in the form of sharpened, small diameter metal wires which can penetrate into tissue as they are advanced from a target site within the treatment region, as described in more detail hereinafter. The electrode elements, however, can also be formed in other manners, such as blades, helices, screws, and the like. The primary requirement of such electrode elements is that they can be deployed in an array, preferably a three-

dimensional array, emanating generally from a target site within the treatment region of the tissue. Generally, the electrode elements will be first introduced to the target site in a radially collapsed or other constrained configuration, and thereafter advanced into the tissue from a delivery element in a divergent pattern to achieve the desired three-dimensional array. Preferably, the electrode elements will diverge radially outwardly from the delivery element (located at the target site) in a uniform pattern, i.e. with the spacing between adjacent electrodes diverging in a substantially uniform and/or symmetric pattern. In the exemplary embodiments, pairs of adjacent electrodes will be spaced-apart from each other in similar or identical, repeated patterns and will usually be symmetrically positioned about an axis of the delivery element. The electrode elements may extend or project along generally straight lines from the target site, but will more usually be shaped to curve radially outwardly and optionally to evert proximally so that they face partially or fully in the proximal direction when fully deployed. It will be appreciated that a wide variety of particular patterns can be provided to uniformly cover the region to be treated.

A preferred form of the individual electrode element of an electrode array is a single wire having a shaped distal portion which can be extended from the delivery element at the target site in the tissue to diverge in a desired pattern. Such wires can be formed from conductive metals having a suitable shape memory, such as stainless steel, nickel-titanium alloys, spring steel alloys, and the like. The wires may have circular or non-circular cross-sections, with circular wires typically having a diameter in the range from about 0.1 mm to 2 mm, preferably from 0.2 mm to 0.5 mm, often from 0.2 mm to 0.3 mm. The non-circular wires will usually have equivalent cross-sectional areas. Optionally, the distal ends of the wires may be honed or sharpened to facilitate their ability to penetrate tissue. The distal ends of such wires may be hardened using conventional heat

treatment or other metallurgical processes. Such wires may be partially covered with insulation, although they will be at least partially free from insulation over their distal portions which will penetrate into the tissue to be treated. In the case of bipolar electrode arrays, it will be necessary to insulate the positive and negative electrode wires in any regions where they would be in contact with each other during the power delivery phase. In the case of monopolar arrays, it may be possible to bundle the wires together with their proximal portions having only a single layer of insulation over the entire bundle. Such bundled wires may be brought out directly to a suitable RF power supply, or may alternatively be connected via other (intermediate) electrical conductors, such as coaxial cable, or the like.

The above described electrode characteristics apply only to active electrodes intended to have the desired surgical effect, i.e. heating of the surrounding tissue. It will be appreciated that in monopolar operation, a passive or dispersive "electrode" must also be provided to complete the return path for the circuit being created. Such electrodes, which will usually be attached externally to the patient's skin, will have a much larger area, typically about 130 cm² for an adult, so that current flux is sufficiently low to avoid significant heating and other surgical effects. It may also be possible to provide such a dispersive return electrode directly on a portion of a sheath or elongate member of the system of the present invention, as described in more detail below (generally, when the return electrode is on the sheath, the device will still be referred to as bipolar).

The RF power supply may be a conventional general purpose electrosurgical power supply operating at a frequency in the range from 400 kHz to 1.2 MHz, with a conventional sinusoidal or non-sinusoidal wave form. Such power supplies are available from many commercial suppliers, such as Valleylabs, Aspen, Bovie, and Birtcher.

The plurality of electrode elements will usually be contained by or within an elongate member which incorporates the delivery element, typically a rigid, metal or plastic cannula. The elongate member serves to constrain the individual electrode elements in a radially collapsed configuration to facilitate their introduction to the tissue target site. The electrode elements can then be deployed to their desired configuration, usually a three-dimensional configuration, by extending distal ends of the electrode elements from the elongate member into the tissue. In the case of the tubular cannula, this can be accomplished simply by advancing the distal ends of the electrode elements distally forward from the tube so that they emerge and deflect (usually as a result of their own spring memory) in a radially outward pattern. Alternatively, some deflection element or mechanism could be provided on the elongate member to deflect members with or without shape memory in a desired three-dimensional pattern.

A component or element will be provided for introducing the elongate member to the target site within the treatment region to be treated. For example, a conventional sheath and sharpened obturator (stylet) assembly can be used to initially access the target site. The assembly can be positioned under ultrasonic or other conventional imaging, with the obturator/stylet then being removed to leave an access lumen through the sheath. The electrode elements can then be introduced through the sheath lumen, typically while constrained in the elongate member. The electrode elements are then extended distally beyond the distal end of the sheath into the treatment region of tissue, and the elongate member can subsequently be withdrawn or left in place. RF current can then be applied through the electrodes in either a monopolar or bipolar fashion. With monopolar treatment, a dispersive plate attached externally to the patient is attached to the other lead from the RF power supply. Alternatively, a return electrode having a relatively large surface area can be provided on the elongate member, or the

sheath. In bipolar operation, the individual electrode elements can be connected alternately to the two poles of the RF power supply. Alternatively, one or more additional electrode elements can be penetrated into the tissue and serve as a common electrode connected at the second pole.

Description of the Preferred Embodiment

Referring now to the drawings, in which similar or corresponding parts are identified with the same reference numeral, and more particularly to Figure 1, the volumetric tissue ablation apparatus of the present invention is designated generally at 10 and includes a probe 12 electrically connected to a generator 14.

In experiments with a prototype of the present invention, the inventor utilized a Bovie® X-10 electrosurgical unit for generator 14, to generate radio frequency current at specific energies, using the probe 12 as the active electrode and placing the tissue sample on a dispersive or ground plate. Thus, generator 14 includes at least an active terminal 16 and a return terminal 18, with a dispersive or ground plate 20 electrically connected by conductor 22 to terminal 18.

Probe 12 is comprised of a plurality of electrically conductive wires 24 which are bundled at a proximal end and connected to terminal 16 to conduct RF current therefrom. Wires 24 are threaded through an electrically insulated or non-conductive tube or catheter 26.

Wires 24 are preferably formed of spring wire or other material which will retain memory. As shown in Figure 1, a 10-wire array 28 is formed with each wire 24 arching from catheter 26 in a general "U" shape with each wire substantially uniformly separated, as shown in Figure 2. Thus, array 28 is formed of a plurality of wires 24 curving radially outwardly from the axis of distal end 26a of catheter 26. Wires 24 all extend a length such that a portion of each wire 24 is perpendicular to the axis of tube 26, and preferably continue curving rearwardly back upon

themselves such that wire distal ends 24a are oriented generally parallel to the axis of the tube distal end 26a. As shown in Figure 1, wire distal ends 24a generally lay within a plane orthogonal to the tube distal end 26a, and uniformly spaced-apart from one another.

Because wires 24 are formed of spring steel, they may be drawn within catheter 26, for percutaneous insertion. Once distal end 26a of catheter 26 is in position, sliding wires 24 through catheter 26 will permit the memory of the wires to take the radially disposed shape of the array 28 shown in Figures 1 and 2.

Figure 3 is a sectional view taken through a liver sample 30, showing the results of a prior art 18 gauge straight needle 31 with 1.2 cm of exposed metal when inserted in liver 30 and operated at 20 watts of power, with 100% coagulation current, for a period of 5 minutes. As can be seen in Figure 3, the lesion 32 produced by the single needle has a narrow elliptical (nearly cylindrical) shape with a diameter of approximately 1.2 cm and a length of approximately 2 cm. Figure 3 also shows the effects of very high temperatures near the probe tip with gas formation common with single needle electrosurgical sources, resulting in charred and carbonized tissue 34 immediately around the needle. The charring and associated gas formation at the site of the single needle probes significantly limits the power which may be applied.

Figure 4 is a sectional view through a liver sample 30' showing the necrotic lesion 32' produced by the 10 wire array 28 of probe 12 of the present invention. Probe 12 is located in tissue sample 30' with tube distal end 26a positioned generally centrally at the site at which a lesion is desired. Various methods, known in the art, may be utilized to position probe 12, prior to deployment of wires 24 (shown deployed in hidden lines). Preferably, positioning of tube distal end 26a is confirmed by ultrasound or other imaging techniques. Once tube 26 is appropriately positioned, wires 24 are deployed into tissue 30', the memory of the wire

material causing the wire deployment to take a predetermined array shape.

The applicants utilized the same generator 14 at a power of 60 watts, with 100% coagulation current, for a period of 5 minutes. It can be seen that the necrotic lesion produced by probe 12 is roughly spherical in shape and has a diameter of approximately 3.5 cm. Furthermore, there is no charring evident, indicating no sparking, and a more uniform temperature distribution within the volume of tissue being treated. During testing, it was found that the temperature of the tissue 2 cm away from the access of probe 12 at the end of the 5 minutes was 51.4°C. The same 10 wire probe 12 was used repeatedly at the same settings and produced substantially identical lesions. It was also found that the area of lethal heating may extend at least another centimeter beyond the visible lesion shown in Figure 4, after thermistor measurements were taken during repeated experiments with probe 12.

While Figures 1 and 2 show a general "fountain" shaped array 28 with 10 wires 24, various other array designs are equally suitable, utilizing uniform spacing of the wire distal ends 24a from catheter distal end 26a to produce a symmetrical lesion, or with non-uniform spacing to produce an assymetric lesion. For example, as shown in Figure 5, multiple arrays 28' may be formed spaced longitudinally from one another. This embodiment of the monopolar tissue ablation apparatus is designated generally at 110 and includes a probe 112 electrically connected to generator 14. Probe 112 includes a first wire bundle 124 journaled through a tube 126 with wire distal ends 124a deployable to form a first array 28'a extending from tube distal end 126a. A second wire bundle 125 surrounds tube 126 within an outer tube 127, with wire distal ends 125a deployable to form a second array 28'b projecting from outer tube distal end 127a. The proximal ends 124b and 125b of wire bundles 124 and 125 are electrically connected in common to active terminal 16.

In operation, outer tube 127 is positioned with distal end 127a located at the predetermined site for the lesion. The second array 28'b is then formed by deploying wire ends 125a of second wire bundle 125. Inner tube 126 is then moved axially such that tube distal end 126a is spaced longitudinally from tube distal end 127a. First wire bundle 124 is then deployed such that wire ends 124a form array 28'a longitudinally spaced from array 28'b.

Referring now to Figure 6, a bipolar embodiment of the tissue ablation apparatus is designated generally at 210 and includes a probe 212 electrically connected to a generator 14. Wires 224 are electrically connected to terminal 16 on generator 14 and terminate distally in an array 228 in the same fashion as the array 28 of the first embodiment. However, apparatus 210 includes an integral return path consisting of a return wire 238 coated with an electrically nonconductive material 236, which extends through catheter 226 within the bundle of wires 224, and has a distal end 238a projecting generally centrally within array 228. The proximal end 238b of wire 238 is connected to return terminal 18, to provide an electrical circuit when probe 212 is deployed within tissue. Thus, a dispersive plate is unnecessary.

Referring now to Figure 7, a second bipolar embodiment of the tissue ablation apparatus is designated generally at 310 and includes a probe 312 with wires 324 connected to active terminal 16 of generator 14. Wires 324 project from distal end 326a of tube 326 to form an array 328.

Bipolar apparatus 310 differs from bipolar apparatus 210 of Figure 6, in two ways. First, a collar 340 is attached to the exterior of tube distal end 326a and is electrically connected to return terminal 18 by a conductor 342, to form an electrical return for current supplied by wires 324. Conductor 342 may be affixed to the outside of tube 326, or threaded through tube 326 while electrically insulated from wires 324.

Second, wires 324 have portions 344 which are coated with an electrically insulative material. Portions 344 are spaced-apart along a plurality of wires 324 in order to restrict current flow from selected portions of wires 324 in order to create a more uniform distribution of heat from the remaining exposed portions of wires 324.

A third bipolar embodiment of the tissue ablation apparatus is designated generally at 410 in Figure 8. Bipolar apparatus 410 includes a probe 412 with one set of wires 424 connected to one terminal 16' of a current generator 14', and a second set of wires 425 connected to the opposite terminal 18'. The individual wires of wire bundles 424 and 425 have an electrically insulative coating through tube 426, to prevent electrical contact with one another. Wires 424 and 425 preferably alternate throughout array 428, such that current flows between wires 424 and wires 425.

Description of the Method of the Present invention

Referring now to Figures 9-14, a treatment region TR within tissue T is located beneath the skin S of a patient. The treatment region may be a solid tumor or other lesion where it is desired to treat the region by RF hyperthermia. The treatment region TR prior to treatment is shown in Figure 9.

In order to introduce an electrode array according to the method of the present invention, a conventional sheath and obturator/stylet assembly 500 is introduced percutaneously (through the skin) so that a distal end of the sheath lies at or within a target site TS, as shown in Figure 10. Obturator/stylet 504 is then withdrawn from sheath 502, leaving an access lumen to the target site, as shown in Figure 11. A delivery probe 510 incorporating the features of the present invention is then introduced through the access lumen of the sheath 502 so that a distal end 512 of an outer cannula 515 of the probe lies near the distal end 514 of the sheath 502, as shown in Figure 12. Individual electrodes 520 are then extended distally from the distal end

512 of the probe 510 by advancing cable 516 in the direction of arrow 519, as shown in Figure 13. The electrodes 520 are advanced so that they first diverge radially outwardly from each other (Figure 13), eventually evertting backward in the proximal direction, as shown in Figure 14. If desired, the cannula 515 of probe 510 is then withdrawn proximally over electrode cable 516, and the electrode cable is then attached to an RF power supply 518 in a monopolar manner, also as shown in Figure 14. Radio frequency current may then be applied from the power supply 518 at a level and for a duration sufficient to raise the temperature of the treatment region TR by a desired amount, typically to a temperature of at least 42°C, usually to at least 50°C, for 10 minutes or longer. Higher temperatures will generally require much shorter treatment times.

While the method and system just described employs a separate sheath and obturator/stylet assembly 500 for introducing the treatment electrodes, it will be appreciated that the use of such a separate introducer is not necessary. Alternatively, the electrodes could be introduced through the elongate member, where the elongate member is provided with a self-penetrating element, such as a sharp tip or an electrosurgical tip, to enhance tissue penetration. As a further alternative, a bundle of electrodes could be introduced in any constrained fashion (e.g. a removable ring, soluble sheath, etc.), with the constraint selectively released after they have reached the target site within the treatment region. The present invention thus will encompass use of a variety of specific systems for introducing a plurality of electrodes to the target site in solid tissue, and thereafter releasing and diverging the individual electrode elements into a treatment region surrounding the target site in a desired three-dimensional array or other configuration or geometry.

Whereas the invention has been shown and described in connection with the preferred embodiments thereof, many modifications, substitutions and additions may be made which

are within the intended broad scope of the appended claims. It can therefore be seen that the volumetric tissue ablation apparatus of the present invention provides an effective and desirable electrosurgical ablation system which is suitable for percutaneous and open surgical introduction, produces uniform lesions, and produces lesions large enough to treat a large spectrum of patients.

I claim:

1. A probe system for penetrating a plurality of electrodes into solid tissue, said probe comprising: an elongate member having a proximal end and a distal end; and at least three solid-tissue-penetrating electrode elements reciprocatably attached to the elongate member, wherein said electrodes are configured to diverge in a three-dimensional pattern as they are advanced in a distal direction from the elongate member.
2. A probe system for penetrating a plurality of electrodes into solid tissue, said probe comprising: an elongate member having a proximal end and a distal end; means for introducing the elongate member through solid tissue; and at least two solid-tissue-penetrating electrode elements reciprocatably attached to the elongate member so that said electrode elements may be advanced into tissue after said elongate member has been introduced through solid tissue to a target site.
3. A probe system as in claims 1 or 2, wherein the elongate member is a tube having an axial lumen which reciprocatably receives the tissue-penetrating electrode elements.
4. A probe system as in claim 2, wherein the introducing means comprises an obturator and sheath assembly, wherein the obturator has a sharpened distal tip and may be removed from the sheath to leave a lumen within the sheath for receiving the elongate member.
5. A probe system as in claim 2, wherein the introducing means comprises a self-penetrating element disposed at the distal end of the elongate member.
6. A probe system as in claims 1 or 2, wherein the tissue-penetrating electrode elements comprise wires which extend through the axial lumen of the elongate member and which have

shaped distal ends, wherein the shaped distal ends assume a radially constrained configuration when the wires are axially retracted within said lumen and assume a radially divergent configuration when the wires are axially extended beyond the distal end of the elongate member.

7. A probe system as in claim 6, wherein the distal ends of at least some of the wires are shaped so that they assume an outwardly everted configuration as they are axially extended beyond the distal end of the elongate member.

8. A probe system as in claims 1 or 2, comprising at least three electrode elements which are configured in a first group and which extend from a first axial position along the elongate member.

9. A probe system as in claim 8, further comprising at least a second group of at least three electrode elements which extend from one or more additional axial positions along the elongate member.

10. A probe system as in claims 1 or 2, wherein the electrode elements are partially insulated over their regions which are advanced into tissue to define a plurality of active electrode surfaces.

11. A volumetric tissue ablation apparatus comprising: a probe system as in any of claims 1-10; an electrical current generator having active and return terminals, wherein at least one of the terminals is connectable to the electrode elements.

12. A volumetric tissue ablation apparatus as in claim 11, wherein the electrical current generator is a radio frequency generator.

13. A volumetric tissue ablation apparatus as in claim 11, wherein both terminals are connectable to the probe system and wherein one terminal connects to one tissue-penetrating-electrode and the other terminal connects to other(s) of the tissue-penetrating-electrodes or to another electrode on the elongate member.

14. A volumetric tissue ablation apparatus as in claim 11, further comprising a dispersive plate connectable to one of the terminals of the electrical current generator.

15. A method for treating a treatment region within solid tissue of a patient with radio frequency current, said method comprising: introducing at least two tissue-penetrating electrodes through solid tissue to a target site within or adjacent to the treatment region; advancing said at least two electrodes from the target site into the solid tissue proximate the target site; and establishing radio frequency current flow between the at least two tissue-penetrating electrodes or between said two electrodes and a common electrode.

16. A method for treating a treatment region within solid tissue of a patient with radio frequency current, said method comprising: advancing at least three tissue-penetrating electrodes into the solid tissue from a target site within the treatment region, wherein the electrodes diverge in a three-dimensional pattern from a target site in the treatment region; and establishing radio frequency current flow among the at least three tissue-penetrating electrodes or between said at least three electrodes and a common electrode.

17. A method as in claim 16, wherein the advancing step comprises positioning the at least tissue-penetrating electrodes symmetrically about an axis extending from the target site into the treatment region.

18. A method as in claim 17, wherein the tissue-penetrating electrodes are evenly spaced from each other as they are advanced.

19. A method as in claim 18, wherein the advancing step further comprises averting the tissue-penetrating electrodes as they are further advanced.

20. A method as in claims 15 or 16, wherein the establishing step comprises applying a radio frequency potential between said tissue-penetrating electrodes and a dispersive plate located externally on the patient.

21. A method as in claims 15 or 16, wherein the establishing step comprises applying a radio frequency potential between said tissue-penetrating electrodes and a return or dispersive electrode disposed near the target site.

22. A method as in claims 15 or 16, wherein the establishing step comprises applying a radio frequency potential between said at least two of the tissue-penetrating electrodes.

23. A method as in claims 15 or 16, further comprising introducing an elongate member through solid tissue to the target site, wherein the tissue-penetrating electrodes are carried to the target site by the elongate member.

24. A method as in claim 23, wherein the introducing step comprises penetrating the distal tip of the elongate member through solid tissue to the target site, within the treatment region and wherein the advancing step comprises extending the electrodes from the elongate member after said member has penetrated to the target site.

25. A method as in claim 15 or 16, wherein the introducing step comprises penetrating a sheath-obturator assembly to the target site, removing the obturator from the sheath, and

passing the tissue-penetrating electrodes through a lumen of the sheath.

26. A method as claim 24, wherein the tissue-penetrating electrodes are disposed in a tube having a central lumen and a distal tip when passed through the sheath lumen, and wherein the advancing step comprises advancing said tissue-penetrating electrodes from the lumen of the tube into tissue disposed distally of the distal tip.

27. A method as in claim 24, wherein the tissue-penetrating electrodes are disposed in a tube having a central lumen when passed through the sheath lumen, and wherein the tube is withdrawn proximally over the electrodes prior to advancing the electrodes into tissue.

1/9

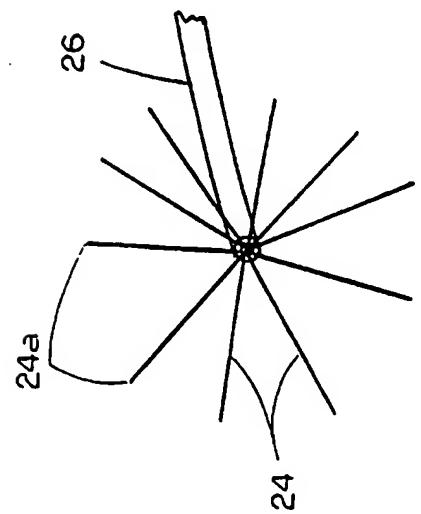


FIG. 2

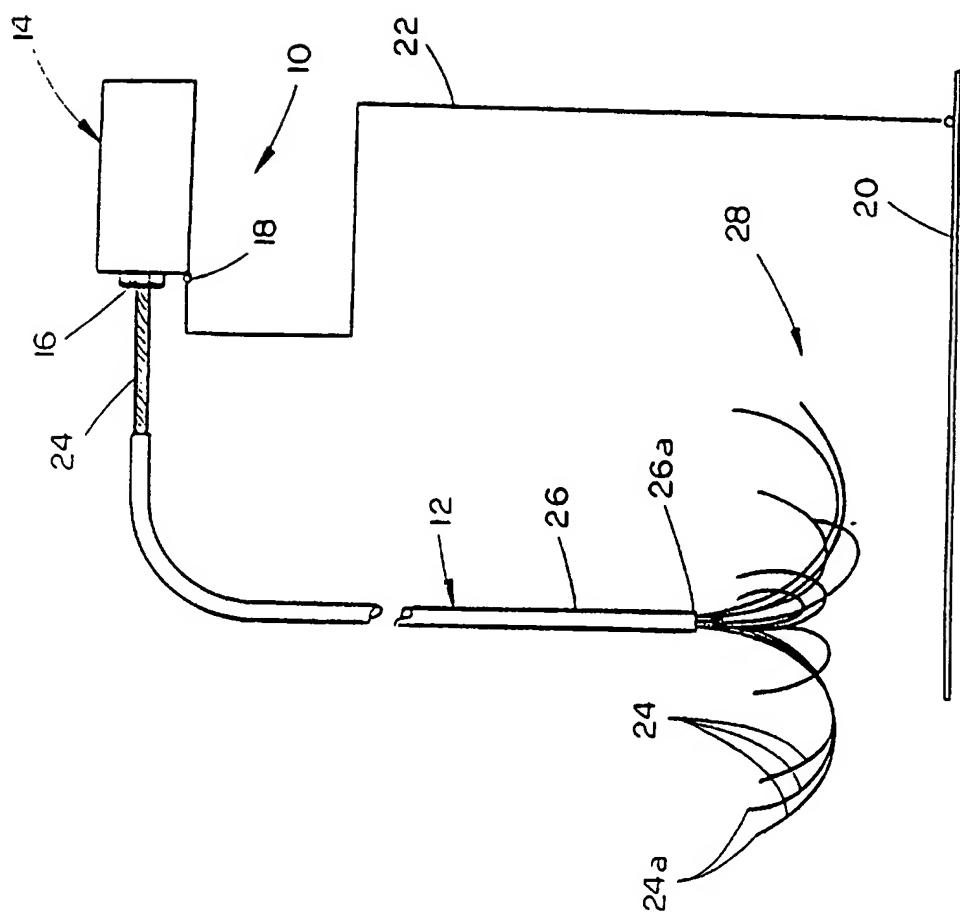


FIG. 1

2/9

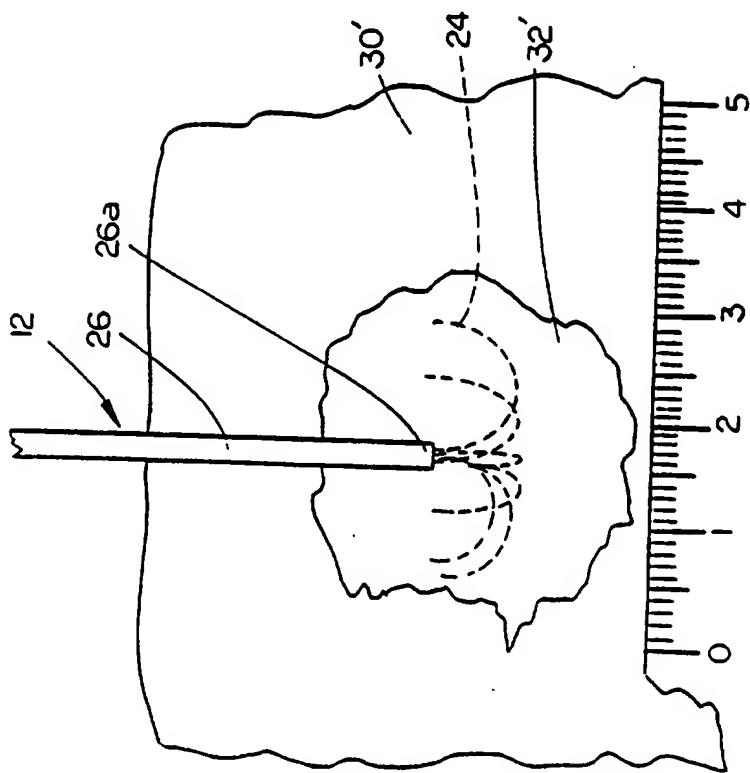


FIG. 4

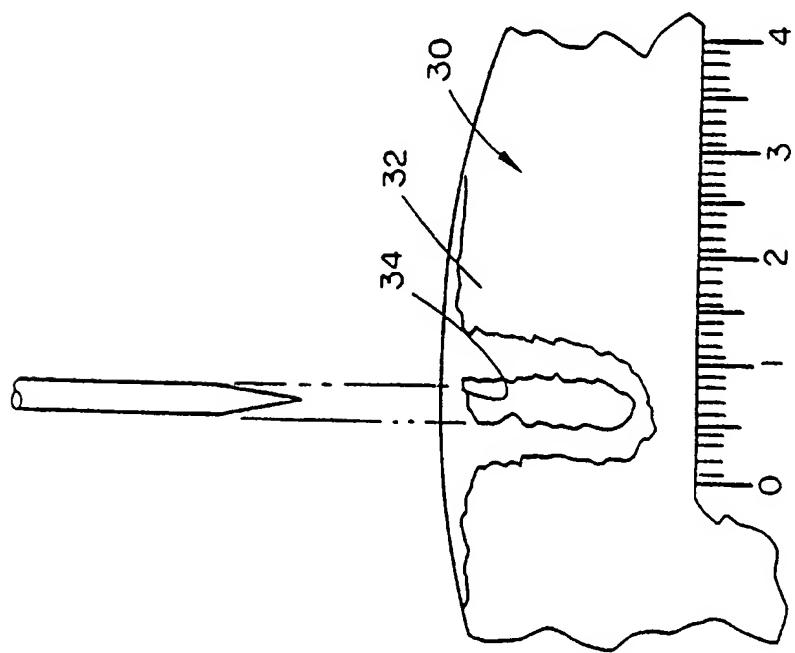


FIG. 3

3/9

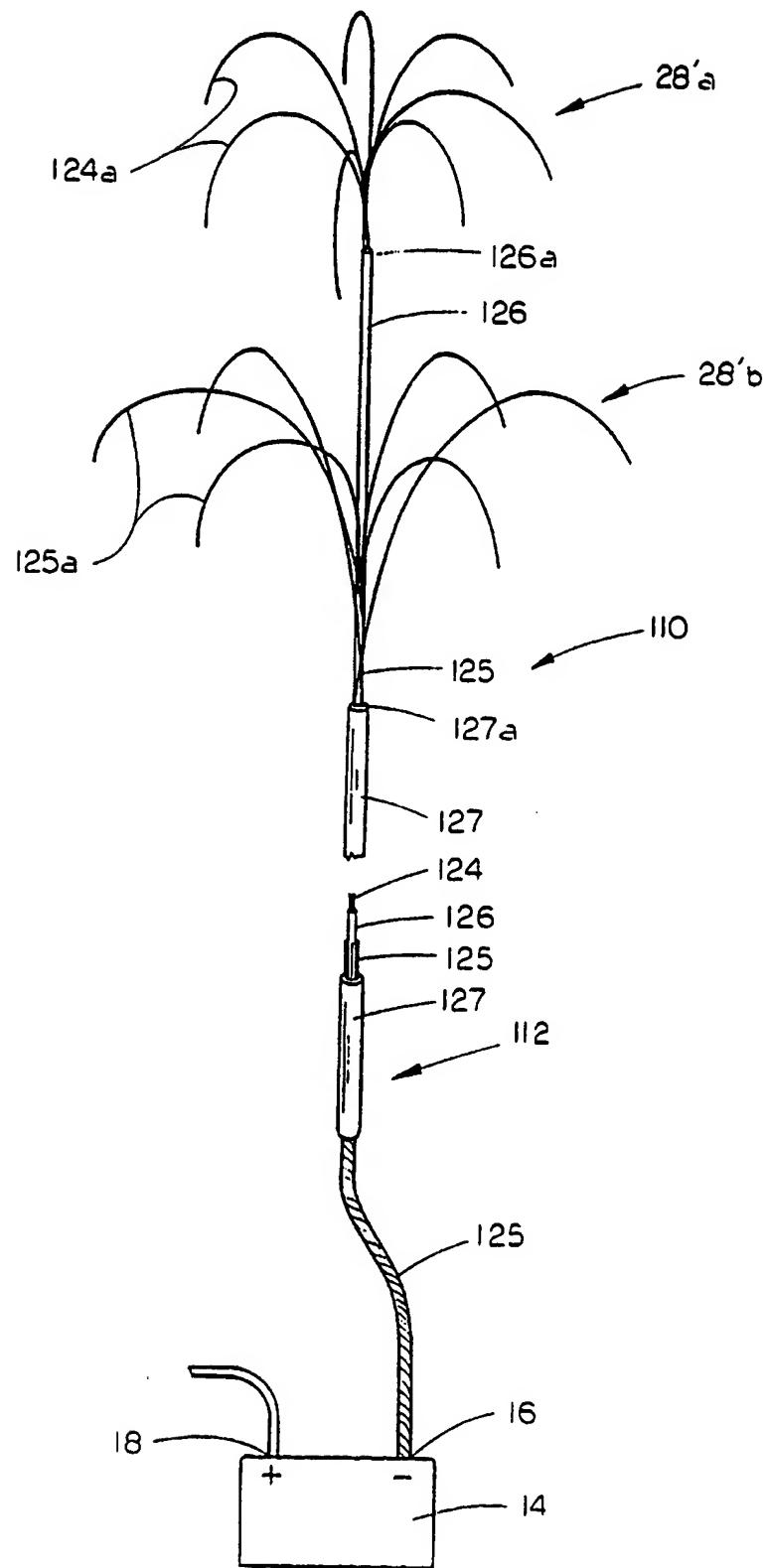


FIG. 5

4/9

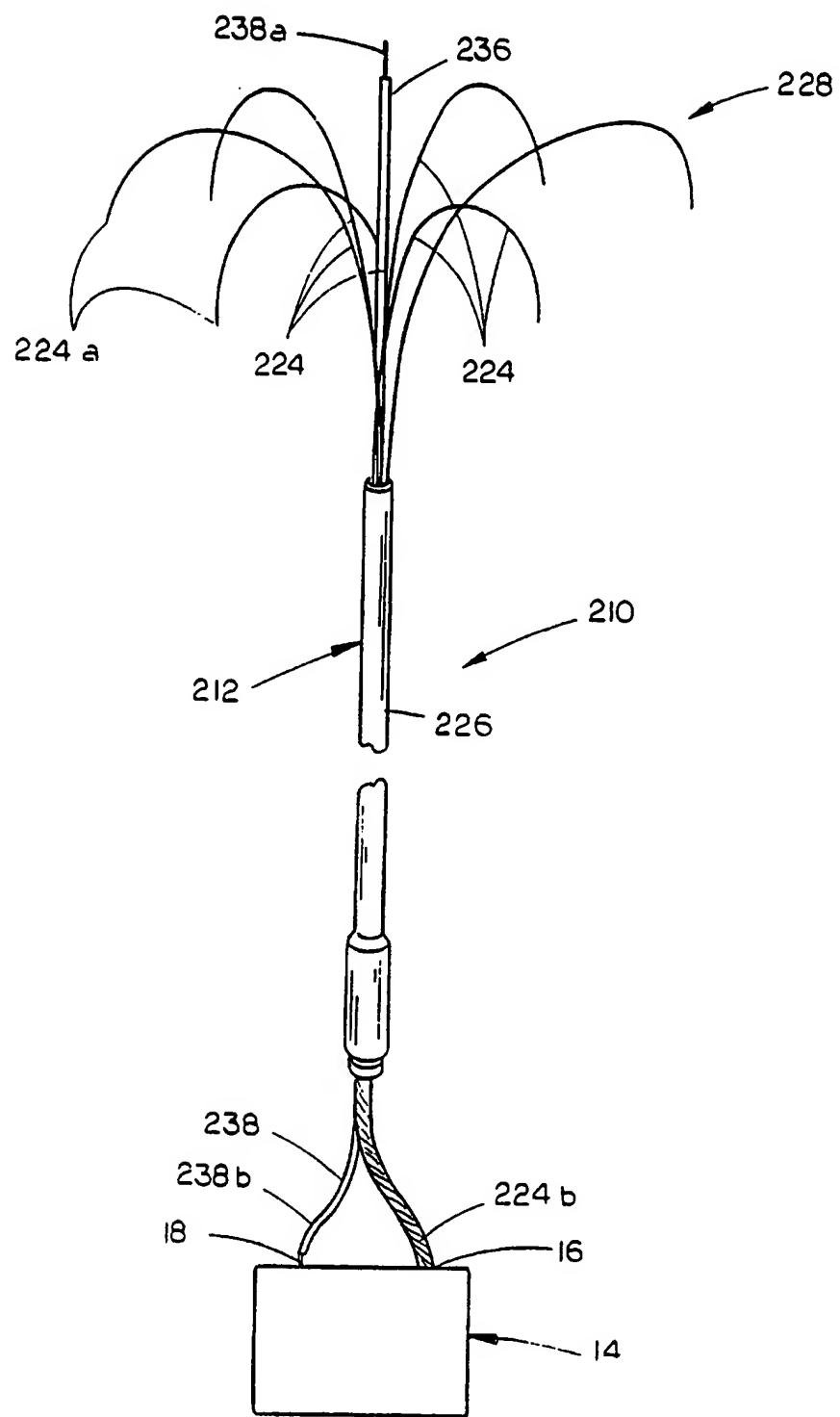


FIG. 6

5/9

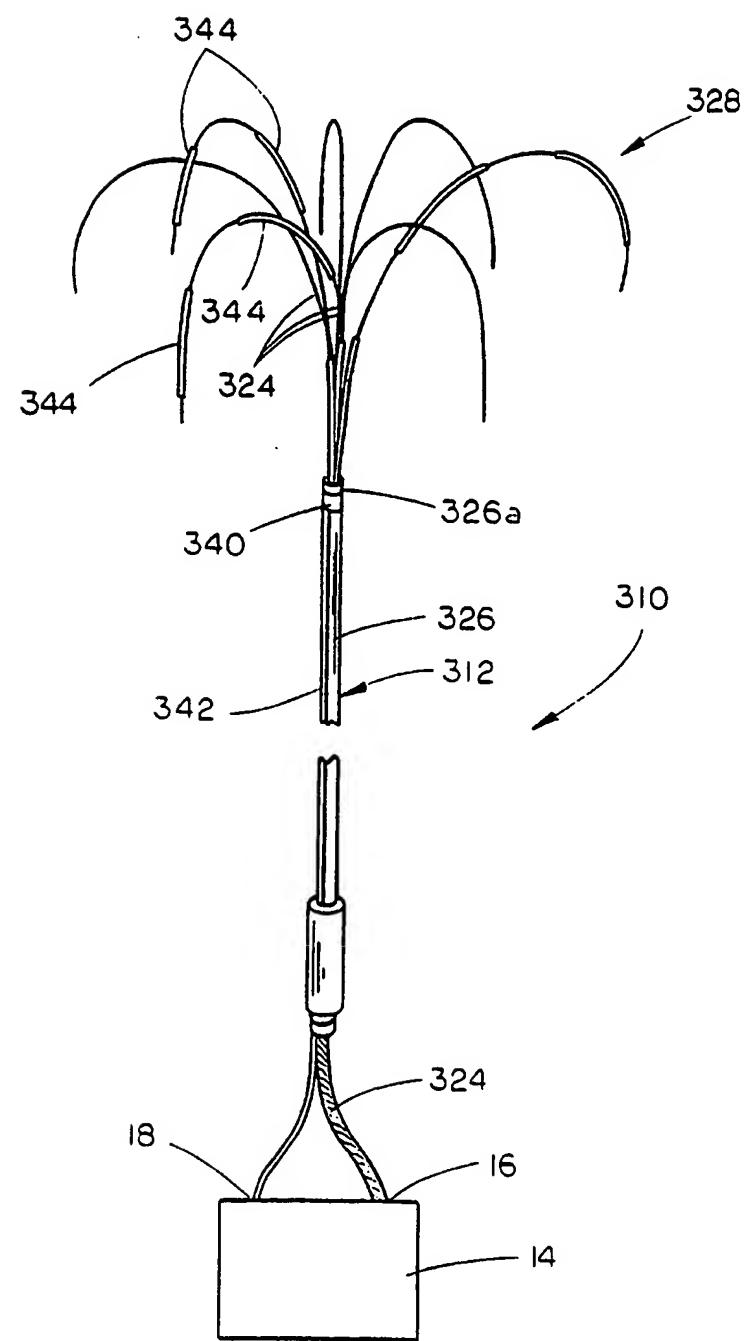


FIG. 7

6/9

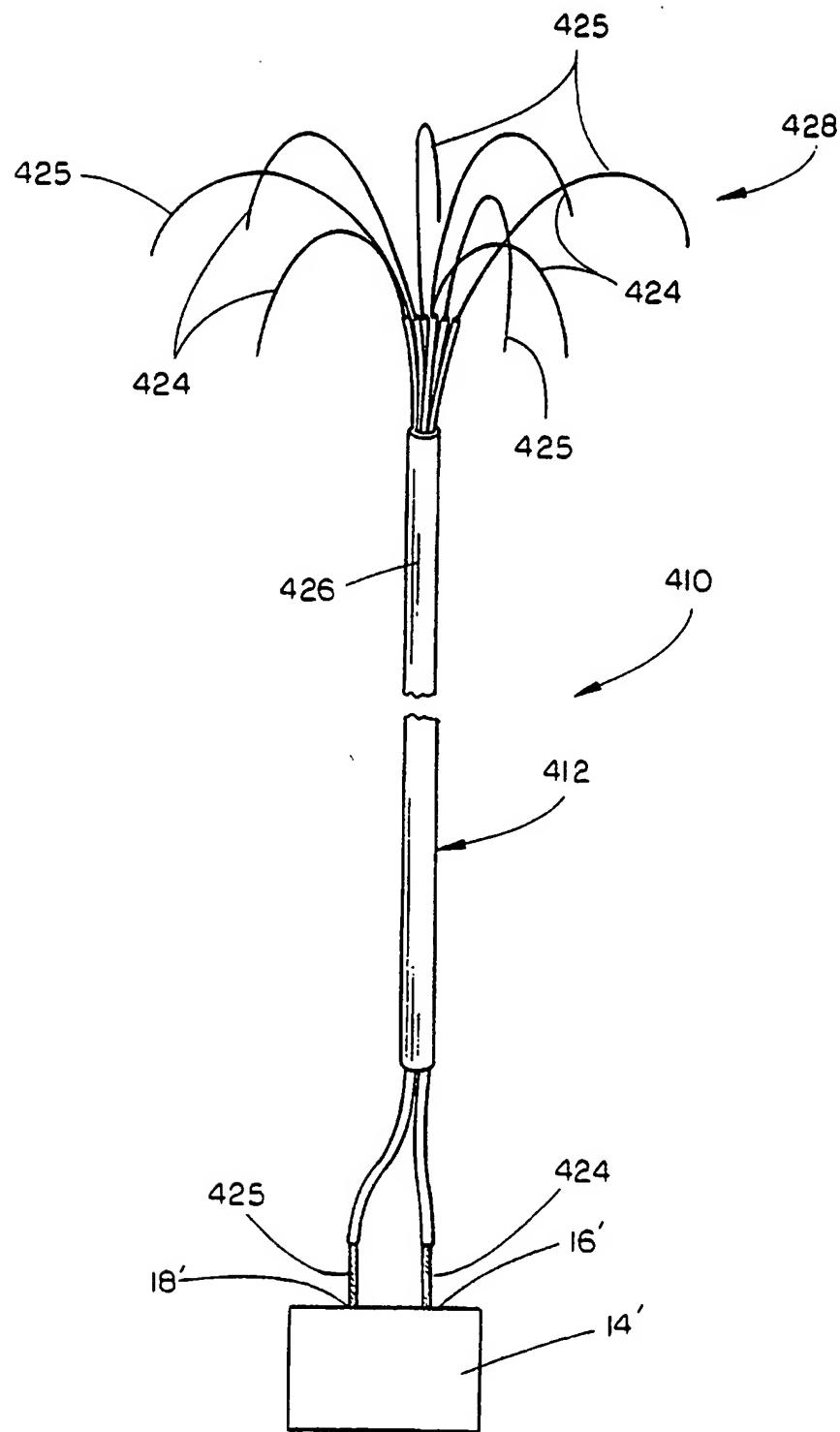


FIG. 8

7/9

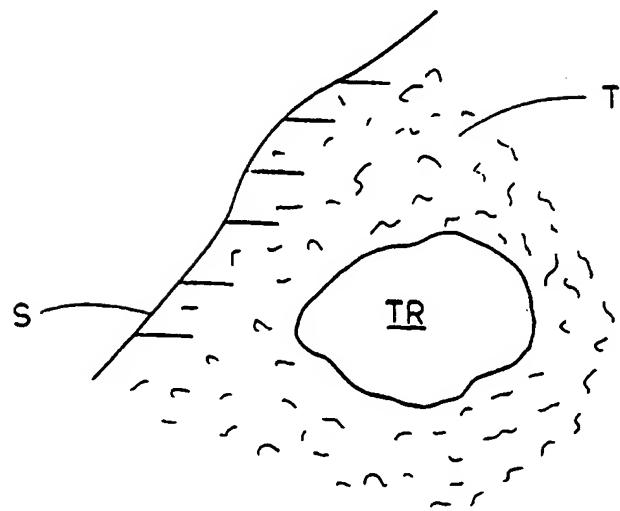


FIG. 9

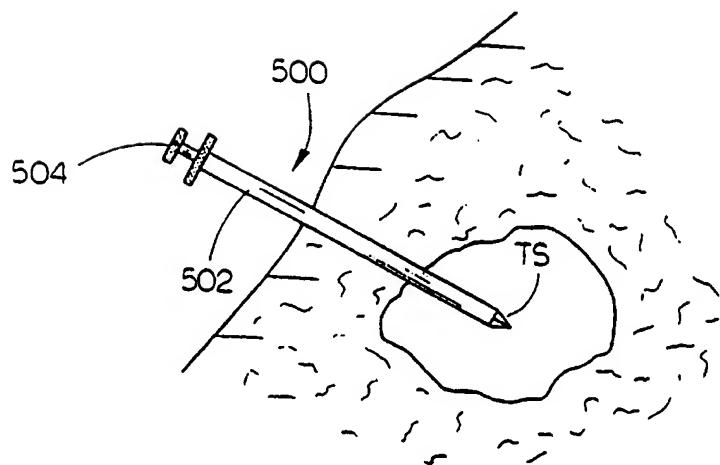


FIG. 10

8/9

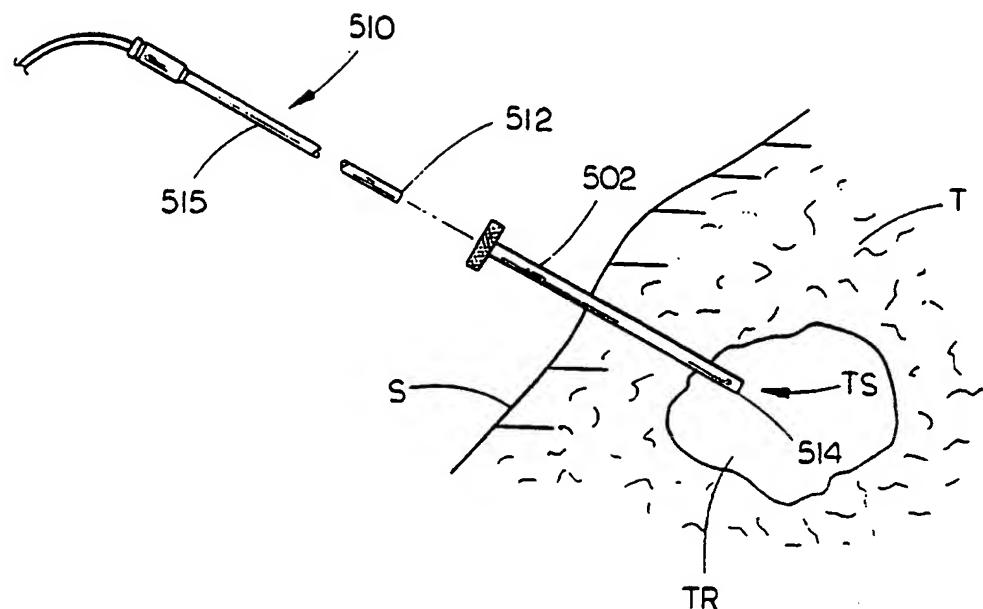


FIG. 11

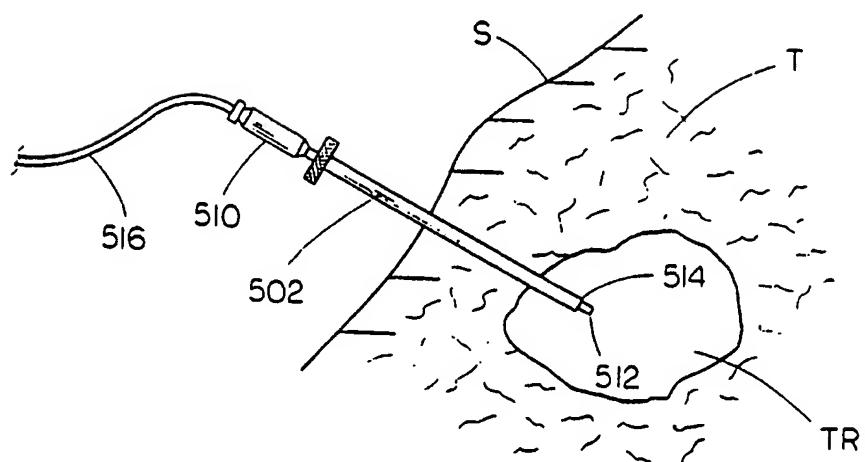


FIG. 12

9/9

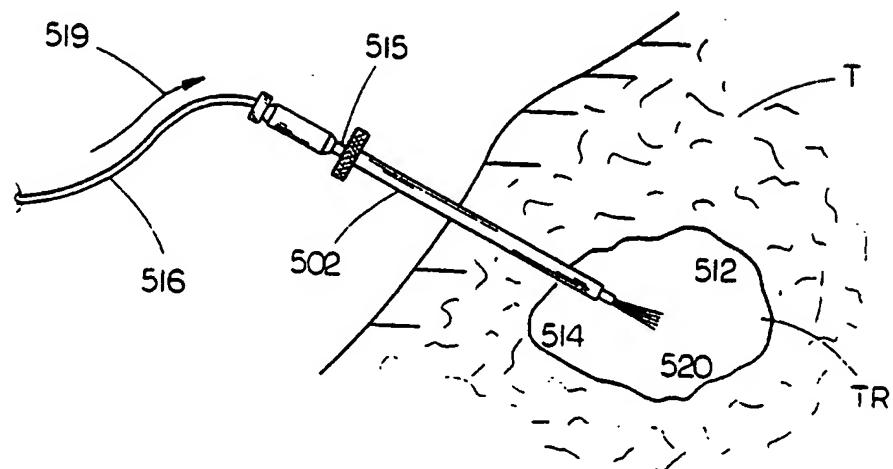


FIG. 13

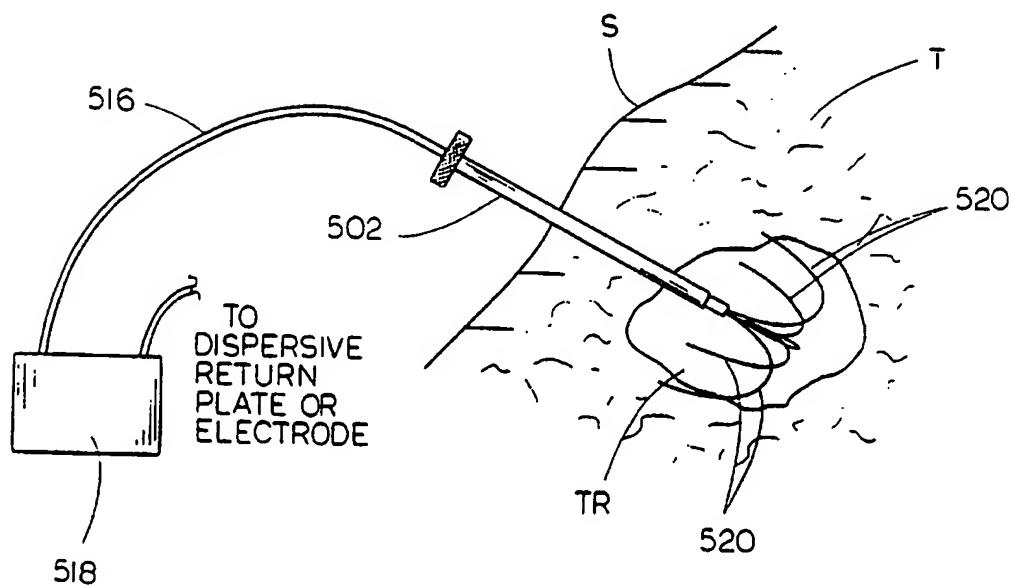


FIG. 14

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 96/03817

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/39

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,4 011 872 (OSAMU KOMIYA) 15 March 1977 see figures 5,913 ---	1,2
A	WO,A,94 26178 (VIDAMED) 24 November 1994 see abstract; figures 1,2 ---	1
A	WO,A,93 24066 (L.I.C.A DI ROSSO) 9 December 1993 see abstract; figure 2 ---	1,2
A	US,A,5 395 368 (ELLMAN) 7 March 1995 see abstract ---	1,2
A,P	WO,A,95 13113 (ZOMED) 18 May 1995 see abstract; figures 1,6 ---	1,2 -/-

Further documents are listed in the continuation of box C.

Patent family members are listed in annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *&* document member of the same patent family

1

Date of the actual completion of the international search	Date of mailing of the international search report
29 July 1996	02.08.96
Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Papone, F

INTERNATIONAL SEARCH REPORT

Int'l Application No
PCT/US 96/03817

C(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	WO,A,96 04860 (ZOMED) 22 February 1996 see abstract	1,2
A,P	WO,A,95 18575 (VIDAMED) 13 July 1995 see abstract; figures 10,6 -----	1

1

INTERNATIONAL SEARCH REPORT

...International application No.

PCT/US 96/03817

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: 15-27
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1 (iv)
2. Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

The additional search fees were accompanied by the applicant's protest.

No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int	national Application No
PCT/US 96/03817	

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-4011872	15-03-77	JP-A- 50129291		13-10-75
		JP-A- 50131433		17-10-75
		DE-A- 2513868		02-10-75

WO-A-9426178	24-11-94	US-A- 5385544		31-01-95
		AU-B- 6908794		12-12-94
		EP-A- 0697837		28-02-96
		US-A- 5409453		25-04-95
		US-A- 5486161		23-01-96
		US-A- 5484400		16-01-96
		US-A- 5456662		10-10-95
		US-A- 5514131		07-05-96
		US-A- 5531677		02-07-96

WO-A-9324066	09-12-93	IT-B- 1257200		10-01-96
		AT-T- 131021		15-12-95
		AU-B- 664633		23-11-95
		CA-A- 2134225		09-12-93
		CZ-A- 9402748		15-02-95
		DE-D- 69300975		18-01-96
		DE-T- 69300975		23-05-96
		EP-A- 0642322		15-03-95
		ES-T- 2068801		01-05-95
		HU-A- 68693		28-07-95
		JP-T- 7507217		10-08-95

US-A-5395368	07-03-95	US-A- 5490850		13-02-96

WO-A-9513113	18-05-95	US-A- 5458597		17-10-95
		AU-B- 1051495		29-05-95
		US-A- 5472441		05-12-95
		US-A- 5536267		16-07-96
		US-A- 5507743		16-04-96

WO-A-9604860	22-02-96	US-A- 5536267		16-07-96

WO-A-9518575	13-07-95	AU-B- 1447695		01-08-95
